REMARKS

Claims 11, 21, 22 and 24-39 are pending and under examination in the above-identified application. Claims 34 has been amended above to delete the phrase "a sequence of" in step (a). Claims 11, 22, 34 and 39 have further been amended to delete all recitations referencing colon cancer. Entry of the amendments, which add no new matter, is respectfully requested.

Regarding 35 U.S.C. § 112, First Paragraph (Written Description)

Applicants respectfully traverse the rejection of claim 34 under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, had possession of the claimed invention at the time the application was filed. Applicants respectfully submit that this rejection has been rendered moot by the amendment to claim 34 above and request removal of the rejection of claim 34 under 35 U.S.C. §112, first paragraph, for allegedly lacking adequate written description.

Rejections Under 35 U.S.C. § 102

Applicants respectfully traverse the rejection of claims 22 and 24-38 under 35 U.S.C. § 102(b) as allegedly being anticipated by Sikut et al., *Biochemical and Biophysical Research Communications* 238:612-616 (1997). Although Applicants do not agree that the cited reference anticipates the rejected claims, in an attempt to further prosecution of the pending claims to allowance, claims 22 and 34 have been amended to delete any reference to colon cancer, rendering the rejection moot.

Applicants respectfully traverse the rejection of claims 22, 24-29 and 31-38 under 35 U.S.C. § 102(b) as allegedly being anticipated by Sikut et al., *Int'l J. Cancer* 82(1):52-58 (1999). Although Applicants do not agree that the cited reference anticipates the rejected claims, in an attempt to further prosecution of the pending claims to allowance, claims 22 and 34 have been amended to delete any reference to colon cancer, rendering the rejection moot.

Applicants respectfully traverse the rejection of claims 22, 24-29 and 31-38 under 35 U.S.C. § 102(b) as allegedly being anticipated by Topalovski et al., *Arch. Pathol. Lab Med.* 123:1208-1218 (1999). As a preliminary observation, Topalovski et al.'s study focuses on

primary and secondary breast lymphomas. Lymphomas are cancers that develop in the lymphatic system and are distinct from breast cancer, which develops in tissues of the breast. Furthermore, Topalovski et al., discloses CD43 merely marker that is used, in a panel along with a host of other markers, to immunophenotype the cell type of breast lymphomas as B-cell versus T-cell. Topalovski et al. do not purport to diagnose breast cancer.[1] Rather, Topalovski et al. conducted a "*a retrospective review of 22 cases of breast lymphoma diagnosed* at William Beaumont Hospital, Royal Oak, Mich, during a 30-year period (1963-1994)." *See Abstract.* Thus, the Topalovski et al. expressly state that they reviewed 22 cases of *previously* diagnosed breast lymphoma. Furthermore, the stated objective of Topalovski et al. was "the clinicopathologic and immunophenotypic characteristics of breast lymphomas, the relative frequency of primary and secondary mammary lymphomas." *Id.* To meet their objective, Topalovski et al. used a panel of markers, including CD43, to identify B-cell phenotypic carcinomas via immunophenotyping:

> Using a panel of immunohistochemical stains (CD45RO, CD45RA, CD43, CD3, CD20, CD30, CD68, and HLA-DR), 8 cases demonstrated unequivocal B-cell phenotype and 3 cases had equivocal or weak staining patterns for B-cell markers. We identified no cases of T-cell lymphoma.
>
> *Id.*[2]

Nowhere do Topalovski et al. teach or suggest the claimed methods of breast cancer diagnosis. Anticipation requires that "each element of the claim at issue is found, either expressly described or under the principles of inherency, in a single prior art reference or that the claimed invention was previously known or embodied in a single prior art device or practice." *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983). See *MEHL/Biophile Int'l Corp. v Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (to anticipate, a single reference must teach every limitation of the claimed invention; any limitation not explicitly taught must be inherently taught and would be so understood by a person experienced in the field); *In re Baxter*

[1] As further confirmation that Topalovski et al. do not report on breast cancer, see page 280, first paragraph ". . . these cases represent the largest group of tumors metastatic to the breast." (the term metastatic indicating that the tumor cells did not originate there). Also, the listing in Table 1, states that all tumors are of B-cell lymphoma.

[2] The markers are all directed to detecting B-cell/lymphoma. Estrogen receptor (ER +/-), Progesterone Receptor (PR +/-) and ErbB2/Her2, markers commonly used in the detection/diagnosis of breast cancer were not used by Topalovski et al.

Travenol Labs., 952 F.2d 388, 390 (Fed. Cir. 1991) (the dispositive question is "whether one skilled in the art would reasonably understand or infer" that a reference teaches or discloses all of the elements of the claimed invention); *Continental Can Co. v. Monsanto Co*., 948 F.2d 1264, 1268-69 (Fed. Cir. 1991) (to anticipate, every element of the claims must appear in a single prior art reference, or if not expressly shown, then demonstrated to be known to persons experienced in the field of technology); *In re Samour*, 571 F.2d 559, 562 (CCPA 1978) (the key question is whether a single prior art reference "publicly discloses every material element of the claimed subject matter"). Because Topalovski et al. do not teach all elements of the claimed invention, Applicants respectfully request removal of the rejection of claims 11, 21, 22 and 24-39 under 35 U.S.C. § 102(b) as allegedly being anticipated by Topalovski et al., *Arch. Pathol. Lab Med.* 123:1208-1218 (1999).

Applicants respectfully traverse the rejection of claims 11, 21, 22 and 24-39 under 35 U.S.C. § 102(b) as allegedly being anticipated by Aguilera et al., *Mod. Pathol.* 13(6):599-604 (1999).

Aguilera et al., like Topalovski et al. discussed above, study breast lymphoma, not breast cancer. In particular, Aguilera et al. appears to be directed to a rare form of breast lymphoma, which is T cell derived rather than the more common B-cell breast lymphoma. Aguilera et al., discloses CD43 as one of three markers that were used in combination as a panel solely to identify the cell type of the cancer tissue as T-cell:

> Positive immunoreactivity for CD45RB and T-cell markers CD3, CD45RO, or I3F1 with negative CD20 *was used to determine T-cell immunophenotye*.
>
> p. 600, left hand column, Immunohistochemistry.[3]

Furthermore, as with the Topalovski et al. study described above, Aguilera et al. reviewed cases of *previously* diagnosed breast lymphoma:

> Four cases of T-cell lymphoma that occurred in the breast were retrieved from the fies of the Armed Forces Institute of Pathology from 1990 to 1999. Blocks were available on all cases for immunohistochemical and genotypic studies.

[3] The markers are all directed to detecting T-cell/lymphoma. Estrogen receptor (ER +/-), Progesterone Receptor (PR +/-) and ErbB2/Her2, markers commonly used in the detection/diagnosis of breast cancer were not used by Aguilera et al.

p. 599, Materials & Methods.

Accordingly, Aguilera et al. do not teach or suggest the claimed methods of breast cancer diagnosis. Because Aguilera et al. do not teach all elements of the claimed invention, Applicants respectfully request removal of the rejection of claims 11, 21, 22 and 24-39 under 35 U.S.C. § 102(b) as allegedly being anticipated by Aguilera et al., *Mod. Pathol.* 13(6):599-604 (1999).

Lastly, it is noted that the Office Action fails to specifically address even the expressly recited features of several of the pending dependent claims. Under the Office's policy of compact prosecution, each claim should be reviewed for compliance with every statutory requirement for patentability in the initial review of the application, even if one or more claims are found to be deficient with respect to some statutory requirement. (MPEP §707.07(g)). Accordingly, in the event that the Office maintains the rejection of any of the dependent claims, Applicants respectfully request, in the interests of compact prosecution, that the Office apply art against each feature of each rejected dependent claim, on the record, and with specificity sufficient to support a *prima facie* case of anticipation.

Regarding 35 U.S.C. § 103

Applicants respectfully traverse the rejection of claims 22 and 24-39 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sikut et al., *Biochemical and Biophysical Research Communications* 238:612-616 (1997) and in further view of U.S. Patent Publication 2004/0038207. Although Applicants do not agree that the cited references render obvious the rejected claims, in an attempt to further prosecution of the pending claims to allowance, claims 22, 34 and 39 have been amended to delete any reference to colon cancer, rendering the rejection moot.

Applicants respectfully traverse the rejection of claims 22 and 24-39 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sikut et al., *Int'l J. Cancer* 82(1):52-58 (1999) and in further view of U.S. Patent Publication 2004/0038207. Although Applicants do not agree that the cited references render obvious the rejected claims, in an attempt to further prosecution of the pending claims to allowance, claims 22, 34 and 39 have been amended to delete any reference to colon cancer, rendering the rejection moot.

Applicants respectfully traverse the rejection of claims 11, 21, 22 and 24-39 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Aguilera et al., *Mod. Pathol.* 13(6):599-604 (1999) and in further view of U.S. Patent Publication 2004/0038207.

The examiner bears the burden of establishing a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3 1531, 1532, (Fed. Cir. 1993). The deficiencies of Aguilera et al. are described in detail above. Aguilera et al. is directed to a rare form of breast lymphoma (not breast cancer) that is T cell derived rather than the more common B-cell breast lymphoma. CD43 is mentioned only as one of three markers that were used together as a panel solely to identify the cell type of the previously diagnosed cancer tissue as T-cell. Accordingly, based on the deficiencies of the primary reference as described above and the fact that the cited secondary reference does not cure the deficiencies of Aguilera et al., removal of the rejection of claims 11, 21, 22 and 24-39 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Aguilera et al., *Mod. Pathol.* 13(6):599-604 (1999) and in further view of U.S. Patent Publication 2004/0038207, is respectfully requested.

Lastly, it is noted that the Office Action fails to specifically address even the expressly recited features of several of the pending dependent claims. Under the Office's policy of compact prosecution, each claim should be reviewed for compliance with every statutory requirement for patentability in the initial review of the application, even if one or more claims are found to be deficient with respect to some statutory requirement. (MPEP §707.07(g)). Accordingly, in the event that the Office maintains the rejection of any of the dependent claims, Applicants respectfully request, in the interests of compact prosecution, that the Office apply art against each feature of each rejected dependent claim, on the record, and with specificity sufficient to support a *prima facie* case of obviousness.

CONCLUSION

In light of the Amendments and Remarks herein, Applicant submits that the claims are in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, she is invited to call the undersigned attorney.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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